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L9: Entry 57 of 69 File: USPT Dec 28, 2004

DOCUMENT-IDENTIFIER: US 6835392 B2
TITLE: Dual enhancer composition for topical and transdermal drug delivery

Detailed Description Text (54):
Formulations may also be prepared with liposomes, micelles, and microspheres. Liposomes are microscopic vesicles having a lipid wall comprising a lipid bilayer, and can be used as drug delivery systems herein as well. Generally, liposome formulations are preferred for poorly soluble or insoluble pharmaceutical agents. Liposomal preparations for use in the instant invention include cationic (positively charged), anionic (negatively charged) and neutral preparations. Cationic liposomes are readily available. For example, N[1-2,3-dioleyloxy)propyl]-N,N,N-triethylammonium (DOTMA) liposomes are available under the tradename Lipofectin.RTM. (GIBCO BRL, Grand Island, N.Y.). Similarly, anionic and neutral liposomes are readily available as well, e.g., from Avanti Polar Lipids (Birmingham, Ala.), or can be easily prepared using readily available materials. Such materials include phosphatidyl choline, cholesterol, phosphatidyl ethanolamine, dioleoylphosphatidyl choline (DOPC), dioleoylphosphatidyl glycerol (DOPG), dioleoylphoshatidyl ethanolamine (DOPE), among others. These materials can also be mixed with DOTMA in appropriate ratios. Methods for making liposomes using these materials are well known in the art.

Detailed Description Text (60):
The active agent administered may be any compound that is suitable for topical, transdermal or transmucosal delivery and induces a desired local or systemic effect. Such substances include the broad classes of compounds normally delivered through body surfaces and membranes, including skin. In general, this includes: analgesic agents; anesthetic agents; antiarthritic agents; respiratory drugs, including antiasthmatic agents; anticancer agents, including antineoplastic drugs; anticholinergics; anticonvulsants; antidepressants; antidiabetic agents; antidiarrheals; antihelminthics; antihistamines; antihyperlipidemic agents; antihypertensive agents; anti-infective agents such as antibiotics and antiviral agents; antiinflammatory agents; antimigraine preparations; antinauseants; antineoplastic agents; antiparkinsonism drugs; antipruritics; antipsychotics; antipyretics; antispasmodics; antitubercular agents; antiulcer agents; antiviral agents; anxiolytics; appetite suppressants; attention deficit disorder (ADD) and attention deficit hyperactivity disorder (ADHD) drugs; cardiovascular preparations including calcium channel blockers, CNS agents; beta-blockers and antiarrhythmic agents; central nervous system stimulants; cough and cold preparations, including decongestants; diuretics; genetic materials; herbal remedies; hormonolytics; hypnotics; hypoglycemic agents; immunosuppressive agents; leukotriene inhibitors; mitotic inhibitors; muscle relaxants; narcotic antagonists; nicotine; nutritional agents, such as vitamins, essential amino acids and fatty acids; ophthalmic drugs such as antiglaucoma agents; parasympatholytics; peptide drugs; psychostimulants; sedatives; steroids; sympathomimetics; tranquilizers; and vasodilators including general coronary, peripheral and cerebral.

Detailed Description Text (74):
B. Nonsteroidal Antiinflammatory Agents (NSAIDS)

Detailed Description Text (75):

Suitable nonsteroidal antiinflammatory agents that may be used in the formulations of the present invention include, but are not limited to: propionic acid derivatives such as ketoprofen, flurbiprofen, ibuprofen, naproxen, fenoprofen, benoxaprofen, indoprofen, pirprofen, carprofen, oxaprozin, pranoprofen, suprofen, alminoprofen, butibufen, fenbufen and tiaprofenic acid; acetylsalicylic acid; apazone; diclofenac; difenpiramide; diflunisal; etodolac; flufenamic acid; indomethacin; ketorolac; meclofenamate; mefenamic acid; nabumetone; phenylbutazone; piroxicam; salicylic acid; sulindac; tolmetin; and combinations of any of the foregoing. Preferred NSAIDs are ibuprofen, diclofenac sodium, ketoprofen, ketorolac and piroxicam.

Detailed Description Text (76):
The NSAID or NSAIDs may be co-administered with one or more additional active agents, e.g.: antihistaminic agents such as diphenhydramine and chlorpheniramine (particularly diphenhydramine hydrochloride and chlorpheniramine maleate); corticosteroids, including lower potency corticosteroids such as hydrocortisone, hydrocortisone-21-monoesters (e.g., hydrocortisone-21-acetate, hydrocortisone-21-butyrate, hydrocortisone-21-propionate, hydrocortisone-21-valerate, etc.), hydrocortisone-17,21-diesters (e.g., hydrocortisone-17,21-diacetate, hydrocortisone-17-acetate-21-butyrate, hydrocortisone-17,21-dibutyrate, etc.), alclometasone, dexamethasone, flumethasone, prednisolone, and methylprednisolone, as well as higher potency corticosteroids such as clobetasol propionate, betamethasone benzoate, betamethasone diproprionate, diflorasone diacetate, fluocinonide, mometasone furoate, triamcinolone acetonide, and the like; local anesthetic agents such as phenol, benzocaine, lidocaine, prilocaine and dibucaine; topical analgesics such as glycol salicylate, methyl salicylate, 1-menthol, d,1-camphor and capsaicin; and antibiotics. Preferred additional agents are antibiotic agents, discussed in Section F, infra.

Detailed Description Text (77):
The aforementioned compounds may be administered transdermally using the compositions, system and method of the invention to treat any patient with an NSAID-responsive condition or disorder. Typically, NSAMDs are employed as anti-inflammatory and/or analgesic agents, and accordingly may be used to treat individuals suffering from rheumatic or arthritic disorders, including, for example: rheumatoid arthritis (RA), degenerative joint disease (also known as DJD and "osteoarthritis"); juvenile rheumatoid arthritis (JRA); psoriatic arthritis; gouty arthritis; ankylosing spondylitis; and lupus erythematoses such as systemic lupus erythematosus and discoid lupus erythematosus.

Detailed Description Text (78):
Other potential uses of NSAIDs include, but are not limited to, treating fever (via the anti-pyretic property of NSAIDs) or myocardial infarction (MI), transient ischemic attacks, and acute superficial thrombophlebitis (via inhibition of platelet aggregation). Further non-limiting uses for NSAIDs include either single or adjuvant therapy for ankylosing spondylitis, bursitis, cancer-related pain, dysmenorrhea, gout, headaches, muscular pain, tendonitis, and pain associated with medical procedures such as dental, gynecological, oral, orthopedic, post-partum and urological procedures.

Detailed Description Text (119):
ophthalmic drugs--physostigmine sulfate;

Detailed Description Text (150):
The method may be repeated using other pharmacologically active agents (e.g., other steroids, NSAIDs, peptidyl drugs, etc.; see Section IV), permeation enhancing bases (e.g., other inorganic hydroxides, inorganic oxides, and alkali metal or alkaline earth metal salts of weak acids; see Section IIA), and lipophilic co-enhancers (e.g., methyl laurate, ethyl oleate, propylene glycol monolaurate, propylene glycerol dilaurate, glycerol monolaurate, glycerol monooleate, isopropyl n-

decanoate, and octyldodecyl myristate; see Section IIB) as described herein, and substantially the same results will be obtained.

CLAIMS:

43. The method of claim 1, wherein the drug is selected from the group consisting of: analgesic agents; anesthetic agents; antiarthritic agents; respiratory drugs; anticancer agents; anticholinergics; anticonvulsants; antidepressants; antidiabetic agents; antidiarrheals; antibelminthics; antihistamines; antihyperlipidemic agents; antihypertensive agents; anti-infective agents; antiinflammatory agents; antimigraine preparations; antinauseants; antiparkinsonism drugs; antipruritics; antipsychotics; antipyretics; antispasmodics; antitubercular agents; antiulcer agents; antiviral agents; anxiolytics; appetite suppressants; attention deficit disorder and attention deficit hyperactivity disorder drugs; calcium channel blockers; beta-blockers; antiarrhythmic agents; central nervous system stimulants; decongestants; diuretics; genetic materials; herbal remedies; hormonolytics; hypnotics; hypoglycemic agents; immunosuppressive agents; leukotriene inhibitors; mitotic inhibitors; muscle relaxants; narcotic antagonists; nicotine; nutritional agents; ophthalmic drugs; parasympatholytics; peptide drugs; psychostimulants; sedatives; steroids; sympathomimetics; tranquilizers; vasodilators; and combinations thereof.

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L1: Entry 17 of 19 File: USPT Feb 14, 1989

US-PAT-NO: 4804539
DOCUMENT-IDENTIFIER: US 4804539 A
** See image for Certificate of Correction **

TITLE: Ophthalmic liposomes

DATE-ISSUED: February 14, 1989

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Guo; Luke S. S.	Lafayette	CA		
Redmann; Carl T.	Walnut Creek	CA		
Radhakrishnan; Ramachandran	Palo Alto	CA		

US-CL-CURRENT: 424/450; 264/4.3, 264/4.6, 424/427, 428/402.2, 436/829, 514/912, 514/914, 514/966

CLAIMS:

It is claimed:

1. A liposome composition designed for enhanced binding to ocular tissue, comprising liposomes, each having an outer lipid layer containing:

(a) between about 40-80 mole percent of neutral vesicle forming lipid components selected from the group consisting of (a) neutral phospholipids and between 20-50 mole percent cholesterol and (b) neutral phospholipids with predominantly saturated acyl chains, and

(b) between about 20-60 mole percent of positively-charged vesicle-forming lipid component(s) having (i) 2 aliphatic chains carried on a 3-4 carbon backbone, (ii) a polar atom attached to the backbone at a carbon atom which does not carry an aliphatic chain, (iii) an amine linked to the polar atom through a spacer at least 3 atoms long, and (iv) a net positive charge.

2. The composition of claim 1, wherein the positively charged lipid component is a derivatized phospholipid of the form: ##STR2## where PE-NH.sub.2 is phosphatidylethanolamine, and CO.sub.2 -Y-NH.sub.2 is a basic amino acid, or dipeptide containing at least one basic amino acid.

3. The composition of claim 2, wherein the basic amino acid or dipeptide is selected from the group consisting of lysine, arginine, histidine, ornithine, and dipeptides of these amino acids.

4. The composition of claim 1, which further includes a positively-charged cholesterol derivative having an amine group linked to the 6-membered cholesterol A ring by a carbon-containing spacer arm at least three atoms

long.

5. The composition of claim 4, wherein the derivatized cholesterol has the form:

Ch-O-C-Y-NH.sub.2,

where Ch-OH is cholesterol and Y is a carbon-containing chain at least 2 atoms in length.

6. The composition of claim 4, wherein the derivatized cholesterol has the form:

Ch-NH-Y-NH.sub.2,

where Ch-NH.sub.2 is cholesterol-3-amine, and Y is a carbon-containing chain at least two atoms long.

7. The composition of claim 1, wherein the amine-derivatized lipid component (s) are predominantly amine-derivatized phospholipids, and the liposomes contain 25-45% cholesterol.

8. The composition of claim 1, which further includes a high-viscosity polymer selected from the group consisting of hydroxyethylcellulose, hydroxypropylcellulose, polyvinylalcohol, and Neo-Tears.TM..

9. The composition of claim 1, for the treatment of dry eye, wherein the liposomes are suspended in an aqueous medium having a pH between about 6.2-6.8, and the lipid components making up the lipsosomes are substantially saturated.

10. The composition of claim 9, wherein the aqueous medium contains an iron and calcium chelator, in molar excess of the concentration of iron and calcium in the medium.

11. The composition of claim 9, wherein the liposomes are formulated to contain lipids selected from the group consisting of saturated cholesterol esters and long-chain fatty acid.

12. The composition of claim 9, wherein the liposomes are formulated to contain vitamin A.

13. The composition of claim 9, wherein the liposomes are suspended in an aqueous medium containing a polymer selected from the group consisting of hydroxyethylcellulose, hydroxypropylcellulose, methylcellulose, polyvinyl pyrrolidone, and polyvinylalcohol.

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L9: Entry 63 of 69 File: USPT Oct 1, 2002

DOCUMENT-IDENTIFIER: US 6458387 B1
** See image for Certificate of Correction **
TITLE: Sustained release microspheres

Drawing Description Text (8):
FIG. 7 is a bar graph showing the amount of expressed gene product by beta -galactosidase activity in milliunits versus microsphere formation for naked DNA, cationic liposomes containing DNA, and DNA microspheres.

Detailed Description Text (3):
The microspheres are useful for a wide variety of separations, diagnostic, therapeutic, industrial, commercial, cosmetic, and research purposes or for any purpose requiring the incorporation of and stabilization of an active molecule, reactant or drug. Thus, the microspheres of the invention are useful for medical and diagnostic applications, such as drug delivery, vaccination, gene therapy and histopathological or in vivo tissue or tumor imaging. Accordingly, the microspheres are suitable for oral or parenteral administration; mucosal administration; ophthalmic administration; intravenous, subcutaneous, intra articular, or intramuscular injection; administration by inhalation; and topical administration.

Detailed Description Text (10):
The microspheres may be administered to a human or animal by oral or parenteral administration, including intravenous, subcutaneous or intramuscular injection; administration by inhalation; intra articular administration; mucosal administration; ophthalmic administration; and topical administration. Intravenous administration includes catheterization or angioplasty. Administration may be for purposes such as therapeutic and diagnostic purposes as discussed below.

Detailed Description Text (71):
Exemplary antiinflammatory agents include NSAIDS, aspirin, steroids, dexamethasone, hydrocortisone, prednisolone, and Diclofenac Na.

Detailed Description Text (174):
The uptake and expression of the pCMV beta Gal DNA was assayed for efficiency of transfection and amount of expressed beta -galactosidase enzyme. The efficiency of transfection was determined by fixation of the cells and color development with the beta-galactosidase enzyme substrate X-Gal (5-bromo-4-chloro-3-indolyl-beta-D-galactopyranoside, GIBCO-BRL, Gaithersburg, Md.). The amount of expressed beta-galactosidase enzyme was determined by lysing the transfected cells and measuring total enzyme activity with the beta -galactosidase enzyme substrate CPRG (chlorphenolred-beta-D-galactopyranoside, Boehringer Mannheim, Indianapolis, Ind.) Results: The amount of expressed beta -galactosidase enzyme from lysed cells that were transfected using either: 1) naked DNA (no addition); 2) cationic liposomes plus DNA; or 3) DNA-containing microsphere, prepared as described above, is shown in FIG. 7.